DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M2167N

CERTIFIED - RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

October 7, 1998 WL-2-9

Ms. Anna Kane
President and Owner
Trimar Hollywood, Inc.
19265 Vanowen Street
Reseda, CA 91335

Dear Mrs. Kane:

During an inspection of your Trimar Hollywood, Inc., Reseda, California, plasma collection center, on July 30 through August 13,1998, our investigator documented that your firm is in violation of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR Parts 600-680)as follows:

1. Failure to establish scientifically sound and appropriate specifications, standards, and test procedures to assure that blood and blood components are safe, pure, potent and effective in that one donor who had tested repeat reactive for anti-HIV-1/2 was incorrectly viewed to be eligible for further donations when the donor had not met the established criteria for reinstatement. The donor was reentered without Western Blot testing and separate anti-HIV-2 testing on the reentry sample. As a result seventeen (17) unsuitable units of Source Plasma were distributed from thirty-three (33) subsequent donations from this donor. Additionally there is no written procedure for donor reentry [21 CFR 606.140(a), 606.160(e) and 610.45(c)].

2. Failure to follow Standard Operating Procedures (SOPs) for lookback procedure [21 CFR 606.100(b)]. For example,

A donor became repeat reactive for Anti-HCV on 4/14/98. The lookback performed included units collected from [redacted] back to 4/14/97. However, the last negative donation was collected 7/18/97. Lookback should have included all units collected from 7/18/97 back to 7/18/96. As a result, sixty units of source plasma collected and distributed from 4/11/97 back to 7/18/97 were not included in the lookback.

3. Failure to adequately determine donor suitability in accordance with Standard Operating Procedures [21 CFR 640.63 and 606.100(b)]. For example,

a. Source Plasma was collected in January 1998 from a donor who indicated he had been incarcerated for one week in July 1997.

b. Donor [redacted] experienced a ten pound weight loss but was accepted for donation without a documented explanation for the weight loss or an evaluation by the physician prior to donation.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. You should be aware that management at the blood bank was issued an FDA Form 483 at the conclusion of the inspection on 8/13/98 listing Inspectional Observations (copy enclosed). It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions include license suspension and/or revocation and injunction.

Please notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within the 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to:

Robert W. Nicol
Compliance Officer
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445 [redacted]

Sincerely,

Elaine C. Messa

Elaine C. Messa
District Director

Enclosure FDA 483

cc: Louise E. Smith, Examiner
State of California
Department of Health Services
Laboratory Field Services
107 S. Broadway, Room 5016
Los Angeles, CA 90012